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In The

# Supreme Court of the United States

FESTO CORPORATION,

*Petitioner,*

v.

SHOKETSU KINZOKU KOGYO KABUSHIKI CO., LTD., a/k/a SMC CORPORATION and SMC PNEUMATICS, INC.,

*Respondents.*

**On Writ Of Certiorari To The United States Court Of Appeal For The Federal Circuit**

## BRIEF OF AMICUS CURIAE CHIRON CORPORATION IN SUPPORT OF PETITIONER

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## STATEMENT OF INTEREST

Founded in 1981 by scientists at the University of California, Chiron Corporation ("Chiron"), with more than three thousand employees, is one of the world's largest biotechnology companies.[1] Chiron applies biotechnology and other techniques of modern biology, including the rapidly expanding field of genomics, to develop products intended to lower the overall cost of healthcare and improve the quality of life by diagnosing, preventing, and treating disease. To carry out this mission, Chiron invests heavily in biological research: nearly $1.2 billion in the last four years. In return for its investment in research and development over the past twenty years, Chiron's inventions include drugs to treat cancer, multiple sclerosis, and cystic fibrosis; vaccines for hepatitis B, meningococcal C, and whooping cough; and blood tests used worldwide to screen donated blood for HIV and hepatitis C virus.

As do other biotechnology companies, Chiron depends on patent protection to achieve adequate returns on its research outlay to encourage stockholder investment. Chiron now owns over three thousand United States and foreign patents. It has taken a lead role in litigating issues related to biotechnology patent protection, including both infringement actions against companies that seek to use its patented technologies

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[1] Written consent to the filing of this brief has been obtained from the parties and is lodged herewith. Counsel for a party did not author this brief in whole or in part. No person or entity other than the *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

without a license and appeals from Patent and Trademark Office ("PTO") decisions related to issues of patentability. *See, e.g., Genentech, Inc. v. Chiron Corp.*, 220 F.3d 1345 (Fed. Cir. 2000); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993). Chiron also appeared as *amicus curiae* in *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). Thus, from its vantage point on the cutting edge of biotechnology, science, and law, Chiron has a unique perspective on the necessity of the doctrine of equivalents to ensure adequate protection for biotechnology inventions.

## SUMMARY OF ARGUMENT

The biotechnology industry and the consumers of the industry's medical innovations benefit from the strong patent protection provided by a vigorous doctrine of equivalents. Patent protection for biotechnological inventions attracts investment capital to the industry, making possible the research necessary to discover and develop life-saving and life-improving medical treatments. These new drugs and treatments routinely require over ten years for research, development, and regulatory approval.

The doctrine of equivalents has been crucial to the adequate protection of biotechnology inventions. Without benefit of the doctrine of equivalents, biotechnology patents will suffer a significant diminution in value, the industry will find it more difficult to attract investment, and companies could not continue the research necessary to develop new treatments and save lives. Put another way, "[t]ry raising a half-billion dollars in capital to bring a cancer treatment to market without patent protection



for the underlying work." 147 Cong. Rec. E1002 (daily ed. June 5, 2001) (statement of Rep. Coble).

The "complete bar rule" announced in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558, 564 (Fed. Cir. 2000) (*en banc*), conflicts with the policy underlying patent law. Biotechnology inventions illustrate the need for the doctrine of equivalents to protect patentees' property rights against loss from alterations found to be equivalent after a patent is filed. First, many possible modifications to a biotechnology invention that could defeat literal infringement have no substantive impact on the invention. *Festo* provides a roadmap for a would-be copyist to avoid infringement by, for example, substituting a known, interchangeable amino acid at one position of a claimed protein. This sort of substitution would be obvious to one of ordinary skill in the art, and increases the incentive to imitate while decreasing the incentive to innovate. Second, there are after-developed improvements that build upon an invention, adding additional features or properties. The improvement itself may be patentable. That fact, however, should not limit the rights of the inventor whose basic invention is being exploited.

The Court should also consider whether, if a complete bar is necessary to prevent ambiguity in the application of the doctrine of equivalents, the holding of *Festo* should be applied purely prospectively – *i.e.*, to patents issuing from new applications filed after *Festo*. The long-established availability of the doctrine of equivalents has profoundly influenced how inventors draft and prosecute their patent applications, especially in the biotechnology field. Applicants typically submitted broad claims for an invention and narrowed the scope during examination.

Very few applications sailed through prosecution without any amendment.

Because the views of the PTO on the proper form of claims and the content of a patent application in the biotechnology arts has evolved over the years, Patent Examiners have required many amendments of original applications. These amendments had nothing to do with prior art and were typically required under 35 U.S.C. § 112, which provides rules limiting the scope of claims to subject matter that is adequately "disclosed" in the patent application. Prior to *Festo*, in accordance with the decisions of this Court and the Federal Circuit, applicants agreed to claim amendments without expecting to surrender all protection under the doctrine of equivalents. Under *Festo*, the owners of the vast majority of the estimated 1.2 million patents in force today will suffer a significant loss in the property right that existed upon grant of the patent, without due process. The retroactive application of *Festo* may be one of the most significant takings of existing property rights by the federal courts. Because *Festo* announces a new principle of law and reneges on the bargain between the parties to the patent system, it should not be given retroactive effect.

## ARGUMENT

### I. THE BIOTECHNOLOGY INDUSTRY DEPENDS ON A STRONG DOCTRINE OF EQUIVALENTS

#### A. The Complete Bar Rule of *Festo* Represents a Drastic Change in Patent Law that Should Be Made, If at All, by Congress

By holding "that when a claim amendment creates prosecution history estoppel, no range of equivalents is



available for the amended claim element," the *Festo* court has dramatically altered the landscape of patent law. *Festo*, 234 F.3d at 564. This decision "unfairly tips the balance away from patentees and toward competitors by constraining the legitimate rights of patentees to their inventions, even where competitors can reasonably determine the reasons for any amendments and the scope of any subject matter surrendered." *Id.* at 620-621 (Linn, J., dissenting in part). Such a shift in policy may particularly harm an industry like biotechnology where a claimed invention immediately suggests a large number of equivalents. *See id.* at 617 (Michel, J., dissenting in part).

The doctrine of equivalents has been an integral part of the United States patent system for nearly 150 years, since *Winans v. Denmead*, 56 U.S. (15 How.) 330 (1854). In subsequent years, this Court's decisions repeatedly affirmed the vitality of the doctrine and rejected efforts to limit its scope. *See, e.g., Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608-09 (1950) (collecting cases). This Court has reiterated the importance of the doctrine, noting that a patent claim "functions to forbid not only exact copies of an invention, but products that go to 'the heart of an invention but avoids the literal language of the claim by making a noncritical change.' " *Markman v. Westview Instr., Inc.*, 517 U.S. 370, 373-74 (1996) (quoting H. Schwartz, Patent Law and Practice 82 (2d ed. 1995)). Four years ago, in *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997), this Court rejected the "complete bar" rule regarding prosecution history estoppel announced in *Festo*.

Potential infringers must consider the doctrine when evaluating whether to engage in conduct that may infringe a patent. The decision to practice a patented

invention near the borders of its claims is a calculated risk, requiring no more care than in analogous areas of the law. Application of the "insubstantial difference" test for equivalency is no less certain, for example, than application of a "reasonableness" test found in ordinary tort law. *See Warner-Jenkinson*, 520 U.S. at 40. Parties must make judgment calls, and patent attorneys, schooled in claim interpretation and familiar with the technology, are eminently able to make such determinations. That they may sometimes be wrong is no reason to eliminate or severely limit the doctrine. They are also sometimes wrong in opining on literal infringement. *See, e.g., Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1278-79 (Fed. Cir. 1995).

*Festo* will lead to a number of predictable consequences. First, patentees, unable to rely on the doctrine of equivalents, will disclose and claim a greater number of variants of their inventions to attempt to gain protection against insubstantial changes. Such additional disclosures could cause an explosion in the verbiage a patent contains. This change to current patent drafting practice could lead to an even greater reliance on the doctrine of equivalents because narrowly drafted claims allowed by the PTO without any amendment would still be entitled to a range of equivalents. *See Festo*, 234 F.3d at 592 (Plager, J., concurring).

The Court of Customs and Patent Appeals noted that "[t]o require such a complete disclosure would apparently necessitate a patent application or applications with 'thousands' of examples . . . along with information as to whether each exhibits [the property of the invention]." *In re Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976). Because the



additional information disclosed would consist of insubstantial variations, there would be little corresponding public benefit from this added disclosure. Instead of reasonable notice of the scope of claims (including equivalents), competitors would be buried in "an avalanche of trivial information – a result that is hardly conducive to informed decisionmaking." *See TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976) (finding that excessive financial disclosure provides less useful information than concise summaries).

*Festo* also encourages patentees to blur the boundaries of their inventions with broadening terms and imprecise adjectives. *See, e.g., Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 66 (1923) (using "substantial" and "high" to describe a patentable improvement to a papermaking machine); *see generally* 3 D. Chisum, Patents § 8.03[3][c] (2000) (discussing words of degree and relational terms). During examination, a patent examiner must evaluate whether each claim is definite, enabled by the specification, and supported by a written description. 35 U.S.C. § 112. In addition, the examiner must compare each claim to the prior art to determine whether the art anticipated the claim or rendered it obvious. 35 U.S.C. §§ 102, 103. The additional work created by vastly greater numbers of claims per patent and the use of fuzzy terms would increase the time from the filing of a patent application to issuance of a patent.[2]

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[2] Biotechnology patents, which now may take eight or ten years to issue could well take fifteen years instead, leaving the patentee with only a few years of protection. *See, e.g., Hitzeman v. Rutter*, 243 F.3d 1345, 1348 (Fed. Cir. 2001) (Federal Circuit

If this Court affirms the complete bar rule, patents obtained pre-*Festo* in reliance on the doctrine of equivalents could become valueless. Very few patents are granted with claims as originally filed. *See Festo*, 234 F.3d at 638 (Newman, J., dissenting in part). Many patentees accepted claim language amendments suggested by the PTO to facilitate allowance of their patents without intending to surrender claim scope. *See id.* at 622 (Linn, J., dissenting in part). Often, applicants had to amend claims to overcome rejections under 35 U.S.C. § 112 because of the evolving views of the PTO on adequate disclosure of a biotechnology invention. *See, e.g., In re Wands*, 858 F.2d 731, 740 (Fed. Cir. 1988) (finding monoclonal antibody technology enabled). When deciding whether to acquiesce in a PTO request to amend under § 112, patent applicants reasonably relied upon existing precedent holding that assertion of infringement under the doctrine of equivalents was not barred by such amendments as opposed to amendments to overcome prior art.[3] If any

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decision granting priority over nineteen years after filing of original application); *Chiron Corp. v. Abbott Lab., Inc.*, 902 F.Supp. 1103, 1108-1109 (N.D. Cal. 1995) (eight years from filing to issuance).

[3] *See, e.g., Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1362-63 (Fed. Cir. 1983), *overruled by Festo*, 234 F.3d 558. In *Hughes*, claims to a method of controlling a satellite in flight were limited to a ground-based computer and controller carrying out the operation because the examiner alleged the specification enabled no other method. Years later, advances in solid-state electronics enabling production of computers small enough to fly onboard the satellite eliminated the need for the ground-based computer and controller. The accused method was carried out entirely onboard the satellite. The Federal Circuit held that assertion of infringement under the doctrine of



change in the law is appropriate, it should be made by Congress, which can adopt appropriate grandfathering legislation. *See* Section II.B, *infra*.

Lastly, and contrary to the constitutional objective of encouraging public disclosure of useful inventions, the holding of *Festo* may cause companies to rely more heavily on trade-secret protection for their inventions. "The interest of the public is that the bargain of 17 years of exclusive use in return for disclosure be accepted." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489 (1974). Faced with uncertainty that their patents may be rendered valueless by only strict literal reading, inventors may choose to limit early disclosure of certain inventions, especially in unpredictable arts such as biotechnology. *See Angstadt*, 537 F.2d at 503. But for claims to products rather than to processes, because competitors generally can reverse engineer biotechnology products without great difficulty, trade secret protection is often impractical once a potential product reaches the clinical trial stage and can be obtained and analyzed by others. Without the exclusivity offered by reasonable patent or trade secret protection, the biotechnology industry has less of an incentive to innovate, and, consequently, the public interest suffers.

### B. The Public Interest in Biotechnology Innovation Would Be Impaired If the Doctrine Were Eliminated or Cut Back

"It would be difficult to underestimate the effect that biotechnology will have on health care delivery and,

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equivalents was not barred because the amendment was made for § 112 reasons rather than to avoid prior art.

more to the point, on the health care status of the American public and our neighbors throughout the world." 146 Cong. Rec. S144 (daily ed. Jan. 31, 2000) (statement of Sen. Hatch). "Approximately 1,300 biotech companies in this country employ more than 150,000 people. . . . The industry spent nearly $10 billion on research and development in 1998 while revenues totaled $18.4 billion." *Id.* (statement of Sen. Mikulski). "The biotechnology industry relies heavily on patent protection in recouping the costs of bringing new drugs to the market. Furthermore, adequate patent protection is vital in persuading investors to provide the necessary capital to the industry." 141 Cong. Rec. S15221 (daily ed. Oct. 17, 1995) (statement of Sen. Hatch).[4] Biotechnology products include insulin to treat diabetes, drugs to treat AIDS and cancer, human growth hormone to treat dwarfism, and diagnostic tests to ensure the safety of the world's blood supply against viruses such as those causing hepatitis and AIDS.

Much of the explosive growth in biotechnology has resulted from technological advances in the last twenty

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[4] Arthur Andersen recently reported that, based on a survey of 272 senior industry executives in the pharmaceutical, biotechnology, and health care industries (conducted by Knowledge Systems & Research, Inc.), "the development and protection of intellectual property is seen [to be] the most critical area" that drives their organizations' business strategies. Ninety-four percent of the respondents indicated that protecting proprietary research was a critical challenge, and ninety percent identified patent infringement as a critical area. Arthur Andersen, *Patients or Patents? New Andersen Survey Reveals What Matters Most to the 21st Century Healthcare Community*, (April 24, 2001) <http://www.arthurandersen.com/website.nsf/content/MediaCenterNewsDeskPBHsurvey04242001!OpenDocument>.



years. Not coincidentally, this Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980), that a human-made, genetically-engineered, living organism represented patentable subject matter, signaled the beginning of the biotechnology industry itself. The United States has since emerged as the world's leading producer of biotechnology inventions, being the priority country for 63% of the patent families filed worldwide in 1990-94. *See* Lawrence M. Rausch, *International Patenting Trends in Biotechnology Genetic Engineering*, National Science Foundation, Issue Brief NSF 99-351 (June 18, 1999) <http://www.nsf.gov/sbe/srs/issuebrf/sib99351.htm.>. Researchers also rated the United States as having strongest patent system in 1995 among 130 countries around the world. *See* Walter G. Park, *Measuring Global Patent Protection*, (1999) <http://www.fraserinstitute.ca/publications/forum/1999/03/patent___protection.html>; *see also* Walter G. Park and Juan Carlos Ginarte, *Determinants of Patent Rights: A Cross-National Study*, Research Policy, Oct. 1997, at 283-301 (describing methods for comparing strength of patent protection in various countries). *Festo* weakens that crucial patent protection, a result that threatens the leading position of the American biotechnology industry.

### C. *Festo* Drastically Limits the Scope of Protection for Biotechnology Patents

To understand the special importance of the doctrine of equivalents to biotechnology patents, a modicum of background in biology is helpful. All living organisms contain genetic material, usually made of DNA (deoxyribonucleic acid). Smaller molecules, called nucleotides, are arranged in a DNA molecule like beads on a string.

Only four nucleotides, typically labeled A, T, C, and G, comprise DNA, but a single strand of DNA may have thousands or millions of nucleotides. "A particular DNA molecule can be graphically represented by listing the nucleotide sequences making up that DNA molecule." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1323 (Fed. Cir. 2001) (*"Mycogen I"*).[5]

DNA contains encoded information that living cells use to build proteins. Proteins are molecules that perform a wide variety of functions in living organisms, from digesting food, to forming muscles, to helping the immune system combat infections. Like DNA, proteins can be described as linear (chain-like) molecules. All protein chains are made from combinations of smaller molecules, called amino acids; there are twenty possible amino acids. The sequence of nucleotides in DNA is the "code" for the sequence of amino acids in a protein. Each group of three nucleotides in a DNA sequence "codes" for one amino acid. In this way, a long molecule of DNA directs the production of a long protein molecule. Living cells have a complex machinery that "reads" a molecule of DNA, taking the sequence information from the DNA molecule and building the corresponding protein. A "gene" is a sequence of DNA that codes for a particular protein.

The doctrine of equivalents is essential for biotechnology patents claiming particular genes or proteins. In biotechnology patent cases, the Federal Circuit has developed a rule that an inventor cannot claim a gene without disclosing its sequence or specific structural

[5] This decision provides useful background information on biotechnology. *See id.* at 1322-24.



information about the gene. *See Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Thus, under the law that the PTO applies during biotechnology patent examinations, it is nearly impossible to write a valid claim for "a DNA sequence that codes for protein X" unless the specification to the patent discloses that the sequence AGGTTAAATCAC etc. that codes for protein X. Therein lies the rub. Because there are sixty-four combinations of three nucleotides (recall that three nucleotides code for one amino acid) and only twenty amino acids, it has been known that several different combinations of nucleotides code for the same amino acid. *See Mycogen*, 243 F.3d at 1323 n.1. For example, nucleotides AGG and CGA both code for the same amino acid. Thus, two seemingly very different strands of DNA can code the same amino acid sequence:

| | |
|---|---|
| AGG·TTA·AAT·CAC·ACT·GAA | *Nucleotides* |
| Arg·Leu·Asn·His·Thr·Glu | *Amino Acids* |
| CGA·CTT·AAC·CAT·ACC·GAG | *Equivalent* |

Without a doctrine of equivalents, a gene patent would be valueless unless it claimed every equivalent sequence of nucleotides. Competitors could avoid infringement simply by substituting nucleotides with others known to be interchangeable. A patentee would need to claim every variant to prevent such unscrupulous copying. Mathematics alone make describing every possible variant impractical. *See In re Bell*, 991 F.2d at 784 (noting that $10^{36}$ nucleotide sequences could code for a

protein called IGF). While no doubt a computer could be programmed to print out every analog, the resulting patent claims would be a stack of paper miles high, and would overwhelm the PTO, as well as those who track patents, with their sheer bulk.[6]

Protein patents present a similar problem. As the Federal Circuit noted in analyzing a patent claim to the protein erythropoietin, "over 3,600 different [protein] analogs can be made by substituting at only a single amino acid position, and over a million different analogs can be made by substituting three amino acids." *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991). A substitution of one amino acid (*e.g.*, leucine) with another amino acid with similar chemical characteristics (*e.g.*, valine) often results in an insubstantially different protein. Even some additions or deletions of amino acids from the sequence of the protein will yield a functionally equivalent protein. Many analogs are functionally indistinguishable, and no purpose would be served by requiring their disclosure.

### 1. The Biotechnology Industry Has a Real Need for a Reasonable Doctrine of Equivalents

One of the *Festo* majority wrote separately to express his opinion that the biotechnology industry's special need for the doctrine of equivalents was "largely theoretical."

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[6] The difficulties of examining DNA and protein patents have forced the PTO to adopt special rules for the presentation of nucleotide or amino acid sequence disclosures. 37 C.F.R. §§ 1.821 *et seq.* (1999); U.S. Department of Commerce, Patent & Trademark Office, *Manual of Patent Examining Procedure* §§ 2420 *et seq.* (rev. ed. Feb. 2000).



*Festo*, 234 F.3d at 597 (Lourie, J., concurring). However, a recent decision demonstrates why the biotechnology industry needs a vital doctrine of equivalents.

*Amgen* obtained a series of patents relating to a recombinant DNA product similar to the natural protein erythropoietin (EPO) – a protein described as being made up of 166 amino acids. *See Amgen, Inc. v. Hoechst Marion Roussel*, 126 F.Supp. 2d 69, 132-133 (D. Mass. 2001) ("*Hoechst*"). A competitor engineered cells to produce a variant that was 165 amino acids in length, deliberately deleting the last amino acid. *See id.* at 133. *Amgen's* claim was not literally infringed. After applying the "function-way-result" test, however, the *Hoechst* court determined that the competitor's variant was equivalent to the claimed EPO. *Id.* at 134.

*Hoechst* demonstrates that skilled scientists can readily recognize and create proteins (and DNA molecules) of equivalent function by making insubstantial changes to a claimed sequence. Amgen's inventors disclosed how to make a protein useful for treating many disease conditions, and their disclosure taught competitors enough to create an equivalent protein. Without a doctrine of equivalents, the value of Amgen's patent would have been lost, even though the deletion of the single amino acid created a molecule which is, for all known relevant biological purposes, the "same" protein. The concern of the biotechnology industry over the loss of the doctrine of equivalents is very real indeed.[7]

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[7] In 1999, Amgen had sales of $1.76 billion of its recombinant EPO product, Epogen®. *Id.* at 77.

### 2. The Doctrine of Equivalents Is Necessary to Alleviate the Uncertainty Caused by the Requirements of Section 112 in Biotechnology Patent Applications

Biotechnology also needs a doctrine of equivalents to allay unpredictability in the application of Section 112 of the Patent Code concerning the allowable scope of claims. For example, an inventor who isolates a particular protein and useful fragments of the protein may claim the protein and fragments. The inventor may attempt to claim all similar protein fragments generally by describing a function of that fragment.

Whether the PTO or courts will allow such a claim depends on an eight-factor test. *See In re Wands*, 858 F.2d at 737. The factors include:

> (1) the quantity of experimentation necessary [to make the claimed invention], (2) the amount of direction or guidance presented [in the specification], (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

*Id.* The complexity of the test emphasizes the difficulty an applicant faces in predicting whether the claims will be allowed based on the patent's specification. *See Amgen*, 927 F.2d at 1212-14. The problem was made more acute for pioneering companies such as Chiron, founded in 1981, which were filing patent applications many years before decisions such as *Wands* and *Amgen* retroactively determined what the contents of those applications should contain. As a result, the requirements of Section



112 alone can severely limit claims. Even a minor narrowing amendment, however, will result in a complete loss of the doctrine of equivalents for the amended claim element under *Festo*.

Without a doctrine of equivalents to temper this unpredictability, decisions in the PTO based on the *Wands* test could cut off legitimate rights to claim an invention and its substantial equivalents. For example, in *Mycogen Plant Sci., Inc. v. Monsanto Corp.*, No. 00-1127, ___ F.3d ___, 2001 U.S. App. LEXIS 18331 (Fed. Cir. August 14, 2001) (*"Mycogen II"*), the Federal Circuit considered whether a patentee was entitled to any range of equivalents for a claim to a particular DNA sequence. *See id.* at *1-*2. The claimed invention addressed the problem of engineering plants to produce a bacterial protein toxin with insecticidal properties ("Bt") at a high enough level to kill insects. *See Mycogen I*, 243 F.3d at 1322. The inventors solved this problem by modifying the bacterial DNA sequence that codes for Bt to a DNA sequence more favored by plants without changing the resulting amino acids. *See id.* at 1324.

The Patent Office, however, rejected claims to a DNA sequence coding for a protein "functionally equivalent" to native Bt that would be highly expressed in plants as not enabled and indefinite. *See* 35 U.S.C. § 112, ¶¶ 1, 2. Mycogen eventually obtained claims directed to a particular disclosed sequence of 1793 or 1833 nucleotides in length. *See Mycogen II*, 2001 U.S. App. LEXIS 18331 at *3-*11. Applying *Festo*, the Federal Circuit limited Mycogen to the literal scope of the claims. *Id.* at *14. Thus, a competitor could completely avoid liability by changing only one nucleotide from the 1833-nucleotide

sequence disclosed by Mycogen – a DNA sequence that would still code for a functional Bt protein.

As *Mycogen II* demonstrates, an inventor's only protection against these losses would be to make and test thousands of potentially useful variants, to describe each in the specification, and to claim each functionally equivalent variant. The extra work involved would slow down patent applications, divert the industry's resources from developing the best commercial embodiments of its inventions, and create a disincentive to disclosing an invention. Alternatively, if the patentee does not describe and enable each potentially useful or functionally equivalent variant in the initial specification, *Festo* would eliminate any range of equivalents – even those equivalents that might be immediately apparent. *Festo* thus offers a Hobson's choice: describe and claim each DNA or protein sequence variant or allow a competitor to practice an equivalent sequence with impunity if a claim to a generic sequence is subject to prosecution history estoppel.

For the reasons explained above, Chiron agrees with the Petitioner that the Federal Circuit's new complete bar rule runs contrary to not only Supreme Court precedent, but also the realities of established patent prosecution practice, and will unfairly impact the biotechnology industry.

## II. THE NEW RULES ANNOUNCED IN *FESTO* SHOULD NOT BE APPLIED RETROACTIVELY

*Festo* overturns the settled expectations of patent applicants based on precedent regarding the doctrine of equivalents. The *Festo* majority announced three new rules of law: (1) that a patentee who amends a claim for



any reason relating to a statutory patentability requirement is subject to prosecution history estoppel, *Festo*, 234 F.3d at 566; (2) that voluntary amendments will create estoppel, *id.* at 568; and (3) that prosecution history estoppel creates a complete bar to application of the doctrine of equivalents, *id.* at 578. These rules "unfairly discount the expectations of a patentee who had no notice at the time of patent prosecution that such [rules] would apply." *Warner-Jenkinson*, 520 U.S. at 41 (Ginsburg, J., concurring).[8] Because these new rules rescind the valuable property interests of patentees who prosecuted patents in justifiable reliance on obtaining a reasonable scope of equivalents, the holding of *Festo* should only be applied prospectively – to patents issuing from new applications filed after *Festo*.

### A. Application of the *Chevron* Factors Demonstrates that *Festo* Should Only Be Applied Prospectively

If *Festo* is upheld and applied retroactively, patentees who obtained their patents prior to the Federal Circuit's decision will suffer a devastating loss of property rights with the elimination of the doctrine of equivalents for a

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[8] On remand, the Federal Circuit acknowledged Justice Ginsburg's concerns and concluded that, when the record was silent as to the reason for an amendment, the patentee should have an "opportunity to establish the reason, if any, for a claim change." *Hilton Davis Chem. Co. v. Warner-Jenkinson, Inc.*, 114 F.3d 1161, 1163 (Fed. Cir. 1997) (*per curiam*). As explained by Judge Newman, *Festo* has made this "rebuttable presumption" irrebuttable. *See Festo*, 234 F.3d at 632-33; *see also Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 238 F.3d 1341, 1345 (Fed. Cir. 2001) (finding that *Festo* barred consideration of a declaration explaining that an amendment was inadvertent).

large class of claims and the delineation of a foolproof method for competitors on how to avoid infringement of such a claim. Accordingly, if the Court accepts the reasoning of *Festo*, significant policy considerations militate against retroactively applying it to the detriment of patentees' investment-backed expectations.

In *Chevron Oil Co. v. Huson*, 404 U.S. 97, 106-107 (1971), the Court identified three factors to consider in determining whether a judicial decision would have a purely prospective effect: (1) whether the decision to be applied non-retroactively establishes a new principle of law, (2) whether retroactive application of the decision serves the purpose and effect of the decision, and (3) whether substantially inequitable results would occur if the decision is applied retroactively. *Id.*

Since *Chevron*, the Court has curtailed the prospective application doctrine. *See, e.g., Harper v. Virginia Dept. of Taxation*, 509 U.S. 86, 97 (1993) (establishing default rule of retroactive application of a new rule of constitutional law where the Court is applying the rule to the parties before it).[9] In so doing, however, the Court has indicated that in some instances, the prospectivity doctrine articulated in *Chevron* remains viable. *See, e.g., Ryder v. United States*, 515 U.S. 177, 185 (1995). In *Ryder*, for instance, the

[9] *Harper* only analyzed retroactivity in the context of the application of a new rule of federal law to third parties when it was applying the rule to the parties before it. *Id.* Accordingly, *Harper* is inapplicable in this case, where the issue is whether the complete bar rule of *Festo* should have a purely prospective effect. As Justice O'Connor has observed, "the question of pure prospectivity [was] not implicated by [*Harper*]." *Id.* at 116 (O'Connor, J., dissenting).



Court applied its decision retroactively but based its conclusion on the fact that the case, which would have affected no more than ten pending cases, did not involve the "grave disruption or inequity involved in awarding retrospective relief . . . that would bring the [*Chevron*] doctrine into play." *Id.*

The Court similarly acknowledged the viability of prospective decision-making in *Reynoldsville Casket Co. v. Hyde*, 514 U.S. 749, 759 (1995). While concluding that a claim of detrimental reliance on preexisting law was insufficient, without more, to justify prospective application of a judicial decision, the Court noted that prospective decision-making could be appropriate where a party demonstrated "*both* reliance interests and other significant policy justifications," conditions that were absent in *Reynoldsville*. *Id.; see also id.* at 761 (Kennedy, J., concurring) (noting that the majority did nothing to erode the Court's "authority to decide that in some exceptional cases, courts may shape relief in light of disruption of important reliance interests or the unfairness caused by unexpected judicial decisions.").

As noted in more detail below, *Festo* eliminates the doctrine of equivalents for a large proportion of the approximately 1.2 million patents in force today, upending the bargained-for property rights of these patent holders without legislative fact-finding, debate, or mandate. This constitutes precisely the kind of exceptional case involving significant policy justifications that warrants application of the *Chevron* prospectivity doctrine, for the complicated policy considerations implicated in diminishing the property rights of hundreds of thousands of patentees are better suited to the legislature than the judiciary. *See, e.g., Chevron U.S.A., Inc. v. Natural Resource*

*Defense Council, Inc.*, 467 U.S. 837, 866 (1984) (noting that "[t]he responsibilities for assessing the wisdom of . . . policy choices and resolving the struggle between competing views of the public interest are not judicial ones" but are properly left to the legislative and executive branches); *accord TVA v. Hill*, 437 U.S. 153, 194 (1978).

### 1. The Complete Bar and the Application of Estoppel to Section 112 Amendments Represent New Principles of Law

The first *Chevron* factor, whether *Festo* applies a new rule of law, clearly favors purely prospective application. Having found that the Supreme Court "has not fully addressed the [scope] of equivalents that is available once prosecution history estoppel applies," the *Festo* majority concluded that it "must independently decide the issue." *Festo*, 234 F.3d at 571. After analyzing a long line of Federal Circuit decisions applying a "flexible bar" approach – that the range of equivalents is limited but not eliminated by prosecution history estoppel – the *en banc* majority overruled the flexible bar approach. *Id.* at 574. Likewise, the *Festo* court also set forth a new rule that amendments to overcome rejections under Section 112 also give rise to prosecution history estoppel. *See id.* at 566-67; *but see Hughes Aircraft*, 717 F.2d at 1362-63 (stating that the Supreme Court had rejected the "wooden application" of prosecution history estoppel to all claim amendments). By overruling a long line of decisions upon which patentees relied, *Festo* completely changed the legal landscape for patentees and their competitors. *See id.* at 612-615 (Michel, J., dissenting in part) (collecting more than fifty Federal Circuit cases applying the flexible bar approach).



### 2. Retroactive Application of *Festo* Does Not Promote the Goals of Certainty and Promoting Innovation

If certainty in the scope of patent claims is the goal of the complete bar rule, that goal is not advanced by applying the rule retroactively to patent applications filed before *Festo*. The premise underlying the new rule is that literal claim scope is readily ascertainable while the scope of the doctrine of equivalents is not. This is demonstrably wrong. The inherent limits in the ability of language to describe inventions create an inevitable amount of uncertainty at the borders of patent claims, whether the infringement asserted is literal or equivalent.

For example, in *Key Pharms. v. Hercon Lab. Corp.*, 161 F.3d 709, 716-17 (Fed. Cir. 1998), the Federal Circuit approved the use of extrinsic evidence to construe the phrase, "a pharmaceutically effective amount." The intrinsic record (the patent and prosecution history) contained no evidence on the point. *Id.* at 718. It can be no less certain to rely entirely on *extrinsic* evidence to determine the literal scope of a patent than to ascertain a scope of equivalents based on the *intrinsic* record.

Applying *Festo* retroactively also does not increase the certainty as to the scope of claims that have issued after argument by the applicant. "Arguments made voluntarily during prosecution may give rise to prosecution history estoppel if they evidence a surrender of subject matter." *Festo*, 234 F.3d at 568. Accused infringers will now assert that arguments made during prosecution surrender subject matter, while patentees will argue the opposite. Courts will still have to make the difficult ultimate determination whether an argument made during

prosecution surrenders claim scope. *See Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1582 (Fed. Cir. 1996) (noting that equivocal nature of argument during prosecution made it difficult to determine whether applicant surrendered subject matter).

Nor will any increased "certainty" in the scope of already-issued patents foster the purpose of promoting innovation. *See Festo*, 234 F.3d at 577. The "new rule hands the unscrupulous copyist a free ride on potentially valuable patented technology, as long as the copyist merely follows the prosecution history roadmap and makes a change, no matter how trivial or insubstantial, to an element otherwise covered by such a narrowed claim limitation." *Id.* at 627 (Linn, J., dissenting in part). Any rule that favors a copyist lessens the incentive to undertake the risks involved in invention. *See Graver Tank*, 339 U.S. at 607 (noting that limiting scope of claims to their literal language "would foster concealment rather than disclosure of inventions"); *see also Festo*, 234 F.3d at 639 (Newman, J., dissenting in part). Experience since *Winans* and *Graver Tank* demonstrates that a healthy range of equivalents promotes, rather than hinders, innovation.

### 3. *Festo* Retroactively Alters the Bargain Between the Patentee and the Government

Reliance on the flexible bar rule and the exemption from estoppel afforded § 112 amendments now leaves many patentees with worthless patents if courts retroactively apply the complete bar of *Festo*. The *Warner-Jenkinson* Court acknowledged that the PTO also may have relied on a flexible rule of estoppel when deciding whether to request an amendment to a claim. *See Warner-Jenkinson*, 520 U.S. at 32 n.6. If a complete bar applies, the



typical patent prosecution practice now leaves a patentee with claims that have no range of equivalents because the practice has been to claim broadly in the initial application and then arrive at an acceptable set of claims through negotiation with the examiner. *See Festo*, 234 F.3d at 592 (Plager, J., concurring). The complete bar rule thus reverses the rules of the game for most existing patents.

The patent process is a bargain between the inventor and the Government. The inventor agrees to disclose an invention to the public in exchange for the Government's agreement to grant a patent on the invention for a term of years. *See Kewanee Oil*, 416 U.S. at 481 (1974). *Festo* retroactively takes away from patentees the consideration they received from the Government in consenting to the disclosure of the invention. Thus, *Festo* destroys the benefit to the patentee in disclosing the invention and instead benefits copyists who add nothing of value to the technology.

The injustice is clearer still in a rapidly-advancing industry like biotechnology when considered in the context of the frequent § 112 amendments applicants have had to make over the years. A consistent justification for the doctrine of equivalents is to accommodate "after-arising technology." *See Warner-Jenkinson*, 520 U.S. at 37. "Because after-arising technology was not in existence during the patent application process, the applicant could not have known of it, let alone surrendered it." *Festo*, 234 F.3d at 620 (Rader, J., dissenting in part). Restricting patentees to the literal language of the patent claim and allowing competitors to use after-developed equivalents with impunity renders a large number of current biotechnology patents "hollow and useless." *See Graver Tank*, 339 U.S. at 607.

The only way for an applicant to avoid estoppel under *Festo* is to show from the intrinsic record that an amendment was not made for reasons of patentability. *Festo*, 234 F.3d at 586. However, "a patentee would have had little incentive to insist that the reasons for all modifications be memorialized in the file wrapper as they were made." *Warner-Jenkinson*, 520 U.S. at 41 (Ginsburg, J., concurring). And patentees have no way now to go back in time and supplement the record to comply with the new rule. Thus, *Festo* turns the "rebuttable presumption" of *Warner-Jenkinson* into an absolute presumption. *See Festo*, 234 F.3d at 632 (Newman, J., dissenting in part).

During the prosecution process, applicants were entitled to rely on the existing law regarding the doctrine of equivalents in deciding whether to accept the bargain offered by the Government. As stated by Justice Frankfurter, "We should not indulge in the fiction that the law now announced has always been the law and, therefore, that those who did not avail themselves of it waived their rights." *Griffin v. Illinois*, 351 U.S. 12, 26 (1956) (Frankfurter, J., concurring). This is not a case where a court interpreted a statute for the first time. Rather, prosecution history estoppel is a long-established, judicially-created doctrine that has been changed, more akin to Congress amending a law. When Congress does amend a law affecting property rights, it takes into account the preexisting rights and the need to grandfather such rights.[10]

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[10] *See, e.g., In re Berg*, 140 F.3d 1428, 1435 n.9 (Fed. Cir. 1998) (finding that patents originally filed before June 8, 1995 were entitled to the *longer* of seventeen years from the date of issue or twenty years from the date of filing pursuant to amendment of 35 U.S.C. § 154 enacted by Pub. L. 103-465 § 532(a)(1) (1994)).



By imposing *Festo* retroactively this Court would punish patentees for behaving rationally under existing law.

### B. Retroactive Application of *Festo* Deprives Patentees of Their Property Rights Without Due Process

In giving its new rules retroactive effect, the Federal Circuit has caused a significant diminution in value in a large percentage of the patents in force today. An inventor has a natural right to his or her discoveries. *See Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966). "[The inventor] may keep his invention secret and reap its fruits indefinitely." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989). Or the inventor can disclose the invention and enjoy a time-limited period of exclusivity from the Government, including, exclusion of those who practice an insubstantial change to the invention. *Festo* eliminates a substantial portion of that exclusivity and destroys the value any existing patents to which the doctrine applies.

A patent provides a right to exclude others from practicing the claimed invention for a limited period of time in exchange for the inventor's contributing her ideas to the public. *See* 35 U.S.C. § 154. If Congress took back part of the compensation the inventor received in the exchange by shortening the patent term retroactively, then the patentee would likely be able to seek just compensation under the Takings Clause of the Fifth Amendment. The *Festo* decision similarly takes a portion of the patentee's property by restricting the right to exclude. Retroactive application of *Festo* represents an uncompensated judicial taking. *See Hughes v. Washington*, 389 U.S.

290, 298 (1967) (Powell, J., concurring) (reasoning that the Takings Clause applies to courts as well as legislatures).

Expressed another way, *Festo* represents the taking of a valuable trade secret by inducing its disclosure in exchange for certain consideration, and then later taking back a portion of that consideration. In *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), Monsanto argued that forced disclosure of its trade secrets pursuant to administrative regulations would constitute a taking requiring just compensation. In response, this Court held that a trade secret was a property interest protected by the Takings Clause. *Id.* at 1003-1004. Because the Court found that the economic value to Monsanto was its competitive advantage by virtue of exclusive access to its trade secrets, it held that the EPA's use or disclosure of Monsanto's trade secrets was a taking for public use. *Id.* at 1016.

In the patent context, an inventor predicates the disclosure of an invention, which until such disclosure is held as a trade secret, on the grant of exclusivity for the claimed invention and a reasonable scope of equivalents. Only when the inventor agrees to a set of claims does she necessarily consent to the disclosure of the invention and the end of her natural property right in the trade secret. "A State cannot be permitted to defeat the constitutional prohibitions against taking property without due process of law by the simple device of asserting retroactively that the property it has taken never existed at all." *Stevens v. City of Cannon Beach*, 510 U.S. 1207, 114 S.Ct. 1332, 1334 (1994) (Scalia, J., dissenting as to denial of writ of *certiorari*). By announcing the complete bar rule, the Federal Circuit has asserted that the patentee "surrendered" a



property right that the court later decided the patentee was not entitled.

Patentees now subject to the complete bar rule have not had an opportunity to be heard "at a meaningful time and in a meaningful manner" as required by the Due Process Clause of the Fifth Amendment. *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). Once the bargain with the Government is complete and the patent issues, an inventor no longer has the option of retreating from the bargain and treating an invention disclosed in a patent as a trade secret. *See Kewanee Oil*, 416 U.S. at 490 (inventor could choose to treat invention as trade secret). Because the rules have been changed for owners of existing patents without an opportunity to be heard, the Court should consider whether the retroactive application of *Festo* conflicts with the Due Process Clause.

## CONCLUSION

Patent protection and the doctrine of equivalents have played a particularly important role in promoting the advancement of the biotechnology industry. *Festo* substantially changes the rules of the game for already issued patents and decreases the incentive to apply for

patents in the future. For the foregoing reasons, the decision below should be reversed or should be limited to purely prospective application.

Respectfully submitted,

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